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IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE  
TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

FILED

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STATE OF TENNESSEE, *ex rel.* ROBERT )  
E. COOPER, JR., ATTORNEY GENERAL, )  
 )  
Plaintiff, )  
 )  
v. )  
 )  
MERCK & CO., INC., a New Jersey )  
corporation, )  
 )  
Defendant. )  
 )

Case No. \_\_\_\_\_

JHmr

STATE OF TENNESSEE'S COMPLAINT  
FOR PERMANENT INJUNCTION AND OTHER RELIEF

This civil law enforcement proceeding is brought in the name of the State of Tennessee, in its sovereign capacity, by and through Robert E. Cooper, Jr., the Tennessee Attorney General and Reporter ("Attorney General", "State of Tennessee" or "State"), and at the request of Mary Clement, the Director of the Division of Consumer Affairs of the Department of Commerce and Insurance ("Director").

The Attorney General brings this action pursuant to the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.* ("TCPA"), in the public interest, to protect the public's health, safety and welfare and pursuant to his general statutory and common law authority powers and duties. *See* Tenn. Code Ann. §§ 8-6-109, 47-18-108(a)(1) and 47-18-114.

The Attorney General and the Director have reason to believe that the above-named Defendant, Merck & Co., Inc. ("Merck") has engaged in unfair and deceptive practices in violation of the TCPA by misrepresenting the safety and efficacy of Vioxx<sup>®</sup>, an anti-inflammatory, non-steroidal drug, in its advertisements and promotions to the public, to prescribers and patients.

Upon information and belief, the State of Tennessee alleges the following:

### **JURISDICTION AND VENUE**

1. The jurisdiction of this Court is invoked pursuant to the provisions of Tenn. Code Ann. § 47-18-108. Venue is proper in Davidson County pursuant to Tenn. Code Ann. § 47-18-108(a)(3), because it is the county where the unfair and deceptive acts and practices alleged in this Complaint took place, or are about to take place, and is the county where Merck conducts, transacts, or has transacted business. The Circuit Court for the State of Tennessee has jurisdiction over Merck pursuant to Tenn. Code Ann. § 47-18-108.

### **PARTIES**

2. Plaintiff, State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General and Reporter, is the duly appointed Attorney General of Tennessee and, as such, has broad statutory and common law powers. The Attorney General is authorized to enforce the TCPA, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Under the TCPA, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the TCPA and to secure such equitable and other relief as may be appropriate in each case under broad grants of statutory and common law authority. Relief available includes but is not limited to, extraordinary relief, restitution, attorneys' fees and civil penalties. *See* Tenn. Code Ann. § 8-6-109 and § 47-18-108(a)(1).

3. Merck is incorporated under the laws and statutes of the State of New Jersey; its principal place of business is One Merck Drive, Whitehouse Station, New Jersey. At all times material to this Complaint, Merck transacted business in the State of Tennessee by advertising, soliciting, selling, promoting and distributing prescription drugs, including Vioxx<sup>®</sup>, to consumers and prescribers in the State of Tennessee.

#### **NOTICE**

4. Prior to filing this Complaint, Merck waived receipt of the notice required by Tenn. Ann. Code § 47-18-108(a)(2).

#### **BACKGROUND**

5. Vioxx<sup>®</sup> is a type of non-steroidal anti-inflammatory drug (NSAID) commonly known as a "selective COX-2 inhibitor" or "COX-2." NSAIDs are widely prescribed to treat the symptoms of arthritis as well as chronic and acute pain from other causes. NSAIDs are highly effective against pain and inflammation; however, they can cause gastro intestinal (GI) side effects, including serious adverse events such as obstructions, bleeds, and perforations.

6. NSAIDs work against pain and inflammation by inhibiting enzymes known as cyclo-oxygenase or COX. There are two forms of COX enzymes: COX-1 and COX-2. COX-1 is involved in the maintenance and repair of the GI system as well as the production of thromboxane, a substance that promotes blood clots. In addition to its role in pain and inflammation, COX-2 is involved in the production of prostacyclin, a substance that helps prevent blood clots. For cardiovascular health, prostacyclin and thromboxane must be in balance.

7. Selective COX-2 inhibitors are NSAIDS that block COX-2 without affecting COX-1. This class of drugs was developed in the 1990s in hope of treating pain and inflammation without blocking COX-1's beneficial effect on the GI system. Unfortunately, it turned out that COX-2 drugs, (*e.g.*, Vioxx®) create an imbalance between thromboxane and prostacyclin that results in an increased risk of heart attack and other adverse cardiovascular events. Any advantage COX-2's have regarding GI safety is offset by increased cardiovascular risk.

#### **DEFENDANT'S COURSE OF CONDUCT**

8. Merck was engaged in trade or commerce throughout the State of Tennessee.

9. Merck, at all times material hereto, solicited consumers and businesses within the State of Tennessee.

10. Merck began marketing Vioxx® in May of 1999 with an aggressive and deceptive promotional campaign directed at both consumers and at health care professionals.

11. When promoting Vioxx® directly to consumers and to health care professionals, Merck misrepresented the cardiovascular safety and the efficacy of Vioxx®.

12. On September 30, 2004, Merck finally admitted that Vioxx® caused serious cardiovascular adverse events and withdrew the drug from the market.

13. For the entire period of time Vioxx® was on the market, Merck's advertisements and promotional activities misrepresented Vioxx®'s cardiovascular safety. Merck's advertisements promoted Vioxx®'s safety and efficacy over cheaper generic NSAIDS, when, in fact, there was little to no evidence that Vioxx® caused less serious GI side effects. Vioxx® actually increased cardiovascular risk.

## **VIOLATIONS OF LAW**

### **TENNESSEE CONSUMER PROTECTION ACT VIOLATIONS**

14. Plaintiff hereby incorporates by reference and re-alleges each and every allegation contained in paragraphs 1 - 13 as if set forth fully herein.

15. By engaging in the aforesaid conduct, Merck has committed unfair and deceptive trade practices, in violation of the TCPA.

16. By engaging in the aforesaid conduct, Merck has violated the Tennessee Consumer Protection Act by committing acts and practices that are unfair, misleading, or deceptive in violation of Tenn. Code Ann. §§ 47-18-104(a) and (b).

17. By engaging in the aforesaid conduct, Merck violated, at a minimum, Tenn. Code Ann. §§ 47-18-104(a), (b)(5) and (b)(7) by misrepresenting that Vioxx<sup>®</sup> had characteristics, uses, benefits, and qualities that it does not have and by engaging in any other act or practice which is deceptive to the consumer or to any other person in violation of Tenn. Code Ann. § 47-18-104 (b)(27).

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General and Reporter, pursuant to the TCPA, the Attorney General's general statutory authority, the Attorney General's authority at common law and this Court's equitable powers, prays:

1. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101, 47-18-108 and 47-18-116 and no court costs or litigation fees or costs of any sort be taxed against the State pursuant to Tenn. Code Ann. § 47-18-116;

2. That process issue and be served upon Defendant Merck requiring the Defendant Merck to appear and answer this Complaint;

3. That this Court adjudge and decree that the Defendant Merck has engaged in the aforementioned acts or practices which violate the Tennessee Consumer Protection Act of 1977;

4. That pursuant to Tenn. Code Ann. § 47-18-108(a)(1) and (a)(4), this Court temporarily and permanently enjoin Defendant Merck from engaging in the aforementioned acts or practices which violate the Tennessee Consumer Protection Act of 1977, and that such orders and injunctions be issued without bond pursuant to Tenn. Code Ann. § 47-18-108(4);

5. That this Court make such orders or render such judgments as may be necessary to disgorge the profits and ill-gotten gains Defendant Merck realized by reason of the alleged violations of the Tennessee Consumer Protection Act of 1977;

6. That this Court enter judgment against Defendant Merck and in favor of the State for the reasonable costs and expenses of the investigation and prosecution of the Defendant Merck's actions, including attorneys' fees, expert and other witness fees, as provided by Tenn. Code Ann. § 47-18-108(a)(5) and (b)(4);

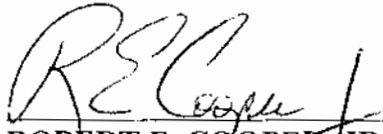
7. That pursuant to Tenn. Code Ann. § 47-18-108(b)(3), this Court adjudge and decree that the Defendant Merck pay civil penalties of not more than one thousand dollars (\$1,000.00) per violation of the Tennessee Consumer Protection Act;

8. That all costs in this case be taxed against Merck, the Defendant, pursuant to Tenn. Code Ann. § 47-18-116; and

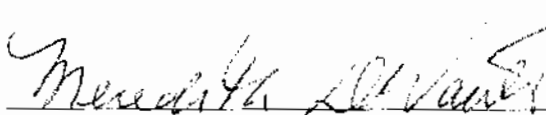
9. That this Court grant Plaintiff, the State of Tennessee, such other and further relief as this Court deems just and proper.

Respectfully submitted,

**FOR THE STATE OF TENNESSEE**  
**Office of the Attorney General & Reporter**



**ROBERT E. COOPER, JR.**  
Attorney General & Reporter  
B.P.R. No. 10934



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